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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,339	12/19/2001	Hans-Peter Harz	13111-00039-US	1787

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EXAMINER	
HANLEY, SUSAN MARIE	

ART UNIT	PAPER NUMBER
1651	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/018,339	HARZ ET AL.	
	Examiner	Art Unit	
	SUSAN HANLEY	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-17,19-21,23 and 27-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-17,19-21,23 and 27-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/3/08; 3/31/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment and response filed 3/31/08 are acknowledged.

Claims 11-17, 19-21, 23 and 27-29 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawal of Rejections

The rejections not explicitly restated below are withdrawn due to Applicant's response in the amendment filed 3/31/08.

New Grounds of Rejection

Applicant's arguments are considered to be moot in light of new grounds of rejection.

Claim Rejections - 35 USC § 103

Claims 1-17, 19-21, 23, 25 and 27-29 are rejected under 35 U.S.C. 103(a) as being obvious over Barendse et al. (US 6,500,426) in view of Jacobsen et al. (US 5,391,371; previously cited) and Millar et al. (US 2,991,226).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed

in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Barendse discloses pelleted enzyme-containing granules. The method of making entails combining a solid carrier, enzyme, edible carbohydrate polymer and water to form a mixture which is processed by low pressure/temperature extrusion. The resulting granules are dried. The disclosure meets, in part, claims 11, 17 and 25. Barendse teaches particle sizes of 480 microns (0.48 mm) and 1080 microns (1.080 mm; examples 2 and 3, respectively) that are species that anticipate the claimed ranges of instant claim 12. The granule can combined with animal feed ingredients, sterilized and pelleted. Pelletizing takes place at 70 degrees C, as in instant claim 29. The edible carbohydrate can be starch, alpha or beta glucans, pectin and glycogen (col. 3, lines 20-45). The solid carrier can comprise a carbohydrate polymer such as starch (col. 3, lines 48-55). The enzyme is a cellulase, protease, esterase or phytase, as in instant claims13-15. The phytase activity is 1,000 to 10,000 U of phytase per gram total weight, as in instant claim 16 (col. 7, line 43). The granulate can comprise an additive such as a salt, as in instant claims 27 and 28 (col. 6, lines 14-25). A granulate composition having an edible carbohydrate has greater pelleting stability compared a granule lacking the

edible carbohydrate. This is shown by a comparison between the enzyme activities of granules and enzyme yield after pelleting in a comparison between examples 7 (has edible carbohydrate) and example 1 which lacks the edible carbohydrate. Thus, Barendse demonstrate the preparation of enzyme-granulates suitable for pelleting with animal feed wherein the addition of edible carbohydrate polymers to the granulate mixture improves pelleting stability. Barendse also teaches that the granulate can be coated, prior to pelleting, to improve the stability of the enzyme to the environment. The coating can comprise a fat, wax, polymer, salt or ointment (col. 5, lines 58-68).

Barendse does not teach that the granulate is coated with any of the claimed polymers, wherein the polymer coating does not melt during pelletizing, the polymer is filler free, the temperature of coating, the amount of coating or that the coating increases the pelleting stability compared to an uncoated granulate.

Jacobsen discloses that the prior art teaches the coating of enzyme-containing fodder components to protect the enzyme from heat during pelleting (col. 1, lines 20-35). Jacobsen discloses that the coating an enzyme-containing T-granulate with a coating agent comprising a high melting wax or fat considerably improves the stability of the enzyme in the pelleting process (claim I and the abstract of Jacobsen). Jacobsen discloses that T-granulate having enzymes have been traditionally coated by PEG (col. 1, lines 44-46). The coating constitutes 1-95%, preferably 15-35% w/w of the granulate surface, as in instant claim 23. The coating takes place at about 70 degrees C (col. 4, lines 23-28).

Millar discloses that wax-like polymers suitable for coating and stabilizing pharmaceutical compositions include PVP, polyvinyl acetate, and polyethylene glycols having a molecular weight of 1500-6000. The disclosure of polyethylene glycols with said molecular weight meets the limitations of polymer (a) of claims 11 and 17.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to coat the granule disclosed by Barendse with a polyethylene glycols having a molecular weight of 1500-6000 prior to combination with a feedstuff and pelleting. The ordinary artisan would have been motivated to do so becasue Barnyards teaches that increasing the pelleting stability of a granulate is important. Bernardse does so by adding an edible carbohydrate to the granulate core to achieve greater stability. Jacobsen teaches that the pelleting stability of enzyme-containing granules is increased by coating the granule with a high melting wax or fat or PEG. Thus, Jacobsen extends the ability to protect enzyme containing granules by coating the granulate itself prior to pelleting. The ordinary artisan would have been motivated to employ polyethylene glycols having a molecular weight of 1500-6000 for the coating because Jacobsen teaches the use of PEG coatings and Millar discloses that said polyethylene glycols of said molecular weight are used as coatings for compositions containing sensitive pharmaceuticals. The ordinary artisan would have had a reasonable expectation that coating an enzyme-containing granule of Barendse with polyethylene glycols having a molecular weight of 1500-6000 would increase pelleting stailbity compared to uncoated granules becsue Jacobsen teaches that said coating with PEG is able to achieve this purpose.

Claims 1-17, 19-21, 23, 25 and 27-29 are rejected under 35 U.S.C. 103(a) as being obvious over Barendse et al. (US 6,500,426) in view of Jacobsen et al. (US 5,391,371; previously cited) and Millar et al. (US 2,991,226) in further view of Goode et al. (US 4,689,297; previously cited).

The disclosure of the combined references is discussed supra.

The combined references do not disclose the coating of granules with other polymers of the claimed molecular weights.

Good discloses a method of preparing a pelletized enzyme-containing particle by coating a hydratable core-particle with an enzyme and then a film-forming macro-molecular material. The initial coating is carried out by suspending the hydratable core particle in a fluidized bed dryer. This disclosure meets the limitations of the preamble of claim 11 because a particle that contains an enzyme is formed. Claims 11 and 17 do not specify the exact nature of the structure of the granulate. A particle is interpreted to be a granulate (e.g., a small grain). The size of the granulate is 150 to 2,000 microns, as in instant claim 12. The second step provides for spraying an aqueous slurry of enzyme onto the enzyme-coated core particles to form a coated granulate that comprises an enzyme mixture with a core. The spraying temperature is 25 to 40 degrees C, as in instant claim 21 (col. 4, lines 57-60). Good discloses that the macro-molecular coating material is a water indispersible or water dispersible polymer including polyethylene glycols (MW 1,000 to 8,000), linear alcohol alkoxylate (MW 1,450 to 2,670), polyvinylpyrrolidone (MW 26,000 to 33,000) as in part (a), (b) and (c) of instant claims 11, 17 and 22, respectively. These polymers are disclosed with no

additions or "fillers" as in instant claim 20. Good teaches that the enzyme can be hydrolases such as lipases or proteases, as in instant claims 13 and 14 (see Good, col. 3, lines 27-40). The coated granule can contain any number of additives, as enumerated by claim 2 of Good.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to coat the granule disclosed by Barendse with any of the polymers disclosed by Goode prior to combination with a feedstuff and pelleting. The ordinary artisan would have been motivated to do so because Barendse teaches that increasing the pelleting stability of a granulate is important. Barendse does so by adding an edible carbohydrate to the granulate core to achieve greater stability. Jacobsen teaches that the pelleting stability of enzyme-containing granules is increased by coating the granule with a high melting wax or fat or PEG. Thus, Jacobsen extends the ability to protect enzyme containing granules by coating the granulate itself prior to pelleting. The ordinary artisan would have been further motivated to employ any of the polymers taught by Goode because they have the same purpose, tht is, to stabilize an enzyme-containing granulate. The ordinary artisan would have had a reasonable expectation that coating an enzyme-containing granule of Barendse with any of the polymers taught by Goode would increase pelleting stailbity compared to uncoated granules becsue Jacobsen teaches that said coating with PEG is able to achieve this purpose. Goode teaches polyethylene glycols having a molecular weight of 1000-8000 is a specie of the polyethylene coating taught by Jacobsen. The additional polymers taught by Goode for coating enzyme-containing granules are in the alternative to glycols having a molecular

weight of 1000-8000. Hence, they are equivalent alternatives and would be expected to achieve the same stailbity results.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-17, 19-21, 23, 25 and 27-29 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims1-22 of U.S. Patent No. 6,500,426 (Barendse et al.) in view of Jacobsen et al. (US 5,391,371; previously cited) and Millar et al. (US 2,991,226) in further view of Goode et al. (US 4,689,297; previously cited).

This rejection has the same content as the rejection under 35 USC 103(a). Essentially, Barendse teaches all of the claimed elements except coating granules with the claimed polymers. Jacobsen supports coating enzyme-containing granules with

polyethylene glycols to improve the stability of said granules to the pelleting process. Millar and Goode disclose polymers that are known to serve as coatings for enzyme-containing granules or sensitive pharmaceutical substances.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to coat the granule disclosed by Barendse with any of the polymers disclosed by Goode prior to combination with a feedstuff and pelleting. The ordinary artisan would have been motivated to do so because Barendse teaches that increasing the pelleting stability of a granulate is important. Barendse does so by adding an edible carbohydrate to the granulate core to achieve greater stability. Jacobsen teaches that the pelleting stability of enzyme-containing granules is increased by coating the granule with a high melting wax or fat or PEG. Thus, Jacobsen extends the ability to protect enzyme containing granules by coating the granulate itself prior to pelleting. The ordinary artisan would have been further motivated to employ any of the polymers taught by Goode because they have the same purpose, tht is, to stabilize an enzyme-containing granulate. The ordinary artisan would have had a reasonable expectation that coating an enzyme-containing granule of Barendse with any of the polymers taught by Goode would increase pelleting stailbity compared to uncoated granules becsue Jacobsen teaches that said coating with PEG is able to achieve this purpose. Goode teaches polyethylene glycols having a molecular weight of 1000-8000 is a specie of the polyethylene coating taught by Jacobsen. The additional polymers taught by Goode for coating enzyme-containing granules are in the alternative to glycols having a molecular

weight of 1000-8000. Hence, they are equivalent alternatives and would be expected to achieve the same stailbity results.

Claims 1 and 13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 17 of copending Application No. 10/280,324 in view of Jacobsen et al. (US 5,391,371; previously cited) and Millar et al. (US 2,991,226) in further view of Goode et al. (US 4,689,297; previously cited).

The '324 application is a continuation of U.S. Patent No. 6,500,426 supra. Claim 17 of '324 is a specie drawn to a method of preparing an enzyme-containing granulate.

The disclosures by Jacobsen et al., Millar et al. and Goode are discussed supra.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to coat the granule disclosed by '324 with any of the polymers disclosed by Goode prior to combination with a feedstuff and pelleting. The ordinary artisan would have been motivated to do so because Jacobsen teaches that the pelleting stability of enzyme-containing granules is increased by coating the granule with a high melting wax or fat or PEG. The ordinary artisan would have been further motivated to employ any of the polymers taught by Goode because they have the same purpose, tht is, to stabilize an enzyme-containing granulate. The ordinary artisan would have had a reasonable expectation that coating an enzyme-containing granule of '324 with any of the polymers taught by Goode would increase pelleting stailbity compared to uncoated granules becsue Jacobsen teaches that said coating with PEG is able to

achieve this purpose. Goode teaches polyethylene glycols having a molecular weight of 1000-8000 is a specie of the polyethylene coating taught by Jacobsen. The additional polymers taught by Goode for coating enzyme-containing granules are in the alternative to glycols having a molecular weight of 1000-8000. Hence, they are equivalent alternatives and would be expected to achieve the same stailbity results.

This is a provisional obviousness-type double patenting rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN HANLEY whose telephone number is (571)272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Hanley/
Examiner, Art Unit 1651

/Sandra Saucier/
Primary Examiner, Art Unit 1651